



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,016	04/15/2004	Bruce D. Detwiler	RPS6116-C1	7493

43971 7590 08/09/2006

CARDINAL HEALTH
7000 CARDINAL PLACE
LEGAL DEPARTMENT - INTELLECTUAL PROPERTY
DUBLIN, OH 43017

EXAMINER

WALCZAK, DAVID J

ART UNIT	PAPER NUMBER
----------	--------------

3751

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,016

Applicant(s)

DETWILER ET AL.

Examiner

David J. Walczak

Art Unit

3751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14,16-28 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14,16-28 and 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Drawings***

The drawings are objected to because in Figure 12, one of the two reference characters 160 should be 150 (see page 16, lines 11-15). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: The first paragraph of the specification should be updated to indicate that application serial no. 10/431,769 has matured into U.S. Patent No. 6,902,335. Appropriate correction is required.

Claim Objections

Claim 24 is objected to because of the following informalities: On line 3 of claim 24, "first frangible seal" should be --second frangible seal--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 11-13, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al. (hereinafter Haber). In regard to claim 1, Haber discloses a dispensing and application apparatus designed to contain a flowable substance comprised of a first compartment 4, a second compartment 8, a first frangible seal 10, a second frangible seal 22, at least one sheet 2 divided by the seals to form the first and second compartments, an applicator 24 having a periphery and joined to the at least one sheet with an applicator bond (see column 5, lines 2-3) and a chamber 20 formed

by the at least one sheet and the applicator (viewing Figure 2, the "chamber" is the empty space surrounding the applicator) and bounded in part by the applicator, the applicator bond and the second seal 22 wherein the first seal 10 separates the first and second compartments and the second seal separates the second compartment and the chamber and wherein the first seal 10 breaks when exposed to a first pressure to thereby create a channel permitting fluid communication between the first and second compartments and the second seal breaks when exposed to a second pressure to thereby create a channel permitting fluid communication between the second compartment, the chamber and the applicator. In regard to claims 7 and 8, the applicator 24 is a porous foam pad. In regard to claim 11, an applicator cover 26 releasably encloses the applicator. In regard to claim 12, the seals are thermal seals (see column 4, lines 1-5). In regard to claim 13, Haber discloses a dispensing and application apparatus containing a flowable substance comprised of two compartments 4 and 8, first and second sheet sections (see Figure 2) connected by a primary seal (at an outer periphery thereof, see Figures 1 and 2) and two frangible seals 10, 22 to form the compartments wherein the frangible seals are designed to break when exposed to a predetermined pressure and thereby create channels permitting fluid communication between the compartments and a chamber 20 and an applicator 24 having a periphery and joined to the first sheet section and the second sheet section with at least one applicator bond (as discussed above, i.e., the bond joins the applicator to the lower sheet section and indirectly joins the applicator to the upper sheet section, see Figure 2) wherein the chamber is formed by the first and second sheet sections and the applicator

and is bounded in part by the applicator, the applicator bond and one frangible seal 22. In regard to claims 21 and 22, as discussed above, Haber discloses a cover and thermal seals.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, 19, 20, 23-26, 28 and 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber. In regard to claims 9 and 19, although the Haber reference does not disclose the use of a flexible laminated foil, the Examiner takes official notice that such foils are commonly employed in the making of such devices in order to effectively create a durable product. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ such foils for the sheet material in order to render the device more durable. In regard to claims 10 and 20, although the Haber reference does not disclose the surface area of the bond, it is the Examiner's position that the bond can be of any suitable surface area (as long as the applicator is securely mounted) without effecting the overall operation of the device, especially since the Applicant has not placed any criticality on the claimed surface area and since it has been held that where the general conditions of a claim are disclosed in

Art Unit: 3751

the prior art, discovering the optimum workable ranges involves only routine skill in the art (see *In re Aller*, 105, USPQ 2336). In regard to claim 23, as discussed above, Haber discloses a dispensing, mixing and application apparatus comprised of a sheet defining compartments having substances therein and a chamber separated by frangible seals.

Although the reference does not disclose the strength of one seal with respect to the other, it does disclose that the seals are "similar" (see column 4, lines 58-61).

Accordingly, it is the Examiner's position that it would have been obvious to one of ordinary skill in the art at the time the invention was made that the each seal can break when exposed to the same (equal) pressure as claimed. Further, it is the Examiner's position that the specific seals can be designed to break under any suitable pressures (including the claimed pressures, since seal 10 must rupture first to mix the solution), depending on the needs of the user, without effecting the overall operation of the device. In regard to claim 24, as discussed above, Haber discloses an applicator 24 bonded to the sheet whereby the chamber is bounded in part by the applicator, the bond and the second frangible seal. In regard to claim 25, the chamber has a dispensing conduit 21 and an end cap 26 so that the conduit can transmit a mixture of the substances to a dispensing point when the cap is removed. In regard to claim 26, the sheet includes first and second sheet sections (see Figure 2). In regard to claim 28, the chamber is bounded in part by the second frangible seal 22. In regard to claims 34 and 35, the applicator 24 defines a porous, absorbent, foam pad. In regard to claims 36-38, as discussed above, the claimed features are considered to be obvious

Art Unit: 3751

modifications of the Haber device. In regard to claim 39, as discussed above, the seals are thermal seals.

Claims 3-6, 14, 16-18, 27 and 30-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Gruenbacher et al. (hereinafter Gruenbacher). In regard to claims 3-6, 16-18 and 30-33, although the seals in the Haber reference are not disclosed as having the claimed chevron shaped stress riser, attention is directed to the Gruenbacher reference which discloses an analogous device wherein the frangible seal includes such a stress riser 14, 17 (wherein the point is oriented in the direction of the compartment 12) in order to better control the rupturing of the seal (see column 4, lines 1-7). Further, the Gruenbacher reference discloses that the particular shape of the stress riser is not critical and can be of any suitable configuration (see column 3, lines 65-67). Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include such chevron shaped stress risers in the seals of the Haber reference (wherein the particular configurations/ dimensions of the stress risers can obviously be of any suitable form) in order to better control the rupturing of the seals. In regard to claims 14 and 27, although the Haber reference does not disclose whether or not the sheets is formed of a single folded sheet or two separate sheets, attention is again directed to the Gruenbacher reference, which discloses that a single sheet is folded to form the device (see column 3, lines 36-41) for the inherent benefit of forming the device from fewer parts. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Haber

Art Unit: 3751

device from a single, folded sheet in order to enable the device to be made from fewer parts.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new grounds of rejection.

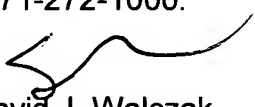
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Walczak whose telephone number is 571-272-4895. The examiner can normally be reached on Mon-Thurs, 6:30- 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3751

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David J. Walczak
Primary Examiner
Art Unit 3751

DJW
8/5/06